REMARKS

The issues outstanding in the Office Action mailed August 26, 2005, are the preliminary amendment, the information disclosure statement, the objection to the disclosure, and the rejections under 35 U.S.C §112, 102, 103 and the doctrine of obviousness-type double patenting. Reconsideration of these issues, in view of the following discussion, is respectfully requested.

Preliminary Amendment

Applicants provide, herewith, a corrected schedule of claims showing claim 9 as previously presented. Claim 9 should have been indicated as "new" in the preliminary amendment. Applicants regret the error.

Information Disclosure Statement

It is noted that the DE reference has been crossed off of the form 1449 accompanying the information disclosure statement, and at page 2 of the Office Action is indicated that the references have been considered "to the extent each is presented in the English language." However, in the information disclosure statement merely makes of record those references which were properly of record in the parent application. As a result, these references *must* be considered by the Examiner herein. An additional copy of the form 1449 listing the German application is provided, and it is respectfully requested that the Examiner initial and return same.

Rejection to the Disclosure

It is argued that no "antecedent basis" or support for the amendment to claim 1 is provided. By this, it is assumed that it is argued that the specification lacks written description of the added language stating that the "preparation possesses improved stability versus one in which a customary binder other than gelatin is used." In fact, the present specification, at page 3, lines 6 - 13 states that the preparation of the invention has "surprising stability" when gelatin is used as a binder. Moreover, this passage states that if gelatin is replaced by "another customary binder", the stability is

greatly reduced. It is well established that claim language need not find express written support in the specification in order to satisfy the written description requirement. Instead, what is necessary is that the specification, as a whole, would teach one of ordinary skill in the art that the Applicants have possession of the concept later claimed. See, for example, *In re Wertheim et al.*, 541 F2d. 257, 191 U.S.P.Q. 90 (CCPA 1976). This is clearly the case herein, where the specification unequivocally teaches one of ordinary skill in the art that the preparations have improved stability versus non-gelatin customary binders. Withdrawal of the objection to the disclosure is therefore respectfully requested.

Rejections Under 35 U.S.C §112

Claims 1 - 6 have been rejected under 35 U.S.C §112, second paragraph as being indefinite. Withdrawal of this rejection is respectfully requested.

At page 2 of the Office Action, it is argued that the recitation that the preparation "possesses improved stability versus one in which a customary binder other than gelatin is used" renders the claim vague and indefinite. Applicants respectfully disagree. It is moreover unclear why this rejection is not applied to claim 9.

In fact, one of ordinary skill in the art clearly understands what materials constitute "customary binders". The formulation art is a mature one, and binders, for example in the preparation of solid tablets, are well known to those of skill. Moreover, measurements of stability are well established in this mature art. One of ordinary skill in the art would have no problem selecting an appropriate test to measure stability of the presently claimed preparations and prior art preparations, and would know when the difference in stability was significant so as to quality as "improved." As such, it is submitted that the claim language is not indefinite. It is moreover submitted that the use of relative terms, e.g., "approach each other" and "closely approximate" do not, per se, result in indefiniteness when they can be easily understood by one of ordinary skill in the art. See *Andrew Corp. v. Gabriel Electronics, Inc.* 847 F.2d819, 6 USPQ2d 2010 (Fed. Cir. 1988). As a result, it is submitted that the claims are fully definite, and withdrawal of this portion of the rejection is respectfully requested.

Finally, in view of the placement of claim 2 into independent from (as new claim 10) it is

submitted that the objection voiced in the penultimate paragraph at page 2 of the Office Action is moot.

Double Patenting

Claims 1 - 6 and 9 have been rejected under the doctrine of obviousness-type double patenting over claims 1 - 4 of the parent patent, U.S. Patent No. 6,491,946. The claims of the '946 patent do not indicate that the composition is free of organic solvent residues. It is not seen that the Office Action addresses why it would be obvious to prepare such a composition. Accordingly, it is submitted that obviousness, as required to sustain a *obvious-type* double patenting rejection, has not been established, and withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C §102

Claims 1, 3 and 9 have been rejected under 35 U.S.C §102(b) over GB '574 (Israel). Reconsideration of this rejection is respectfully requested. At the outset, it is believed that there is a misinterpretation of Israel, in that the Office Action argues that the reference discloses preparation of *levo*-thryoxine. See the Office Action at page 3. In fact, Israel discloses the use of racemic forms of the compound. For example, the application refers to "thryoxine" at column 1 and 2, and discloses the use of "sodium dl-thryoxine" in the example at page 2, column 2, line 101. This is the racemate. The claims of the present application specify that the pharmaceutical preparation comprises an active compound, which "consists essentially of" the l-isomer. Thus, it is submitted that the present claims do not read on the racemate.

Moreover, it is submitted that patentees disclose solely an "injectable" pharmaceutical composition, intended solely for parenteral administration. See page 1, column 1, lines 9-10, where patentees state that the invention "relates to injectable pharmaceutical compositions for the parenteral therapeutic use of thryoxine." Thus, it is submitted that independent claim 9, which specifies that the material is in solid form, does not read upon the reference. Withdrawal of the rejection is therefore respectfully requested. (It is moreover noted that the rejection appropriately has not been applied against dependent claim 5, which also recites a solid preparation.)

Rejection Under 35 U.S.C. §103

Claims 1-6 have been rejected over Israel taken with Reynolds '332. Reconsideration of this rejection is also respectfully requested.

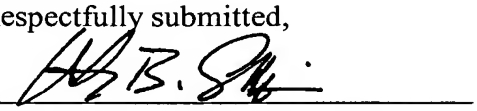
As noted above, Israel teaches solely the use of racemic thryoxine. See, for example, the Abstract at column 1 describing the thryoxine as the free acid. This is the racemate. It is respectfully submitted that one of ordinary skill in the art would not be motivated to employ l-thryoxine, particularly in view of the disclosure of Horster,GB 1,296,510, of record. Column 1, lines 38-40 of Horster teaches that l-thryoxine should not be used, as it has "other metabolic effects" on the heart, circulation and digestion, on protein and on carbohydrate metabolism, which over-shadows any beneficial effect that it might have. In view of Horster's teaching that d-thryoxine is useful, if the material is not "contaminated" with l-thryoxine, see column 1, strong motivation exits to avoid the l-isomer. To the extent that Israel discloses gelatin with racemic preparations of thyroxine, this disclosure pertains to racemic preparations and thus is relevant.

Reynolds, while disclosing l-thyroxine in example V, does not use gelatin as an excipient in this example. Patentees disclose gelatin as part of a laundry list of solid carriers, at column 4, lines 42 - 50. It is respectfully submitted that the use of gelatin, to the extent it is even prima facie obvious over this disclosure for use with the l isomer, is patentable in view of the unexpected results demonstrated in the declaration under 37 C.F.R. 1.132 in the parent. In that declaration, it is shown that, for otherwise equivalent preparations of levothyroxine, the amount of degradation where gelatin is present is significantly reduced over preparations where gelatin is omitted. Since gelatin is shown, arguably, as but one possible selection of excipient, it is submitted that one of ordinary skill in the art would not expect that the use of gelatin provides additional stability over common excipients. Thus, it is submitted that the declaration provides clear evidence of the non-obviousness of the present claim. Withdrawal of the rejection is therefore respectfully requested.

Should the Examiner has any questions or comments, she is cordially invited to telephone the undersigned at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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FILED: November 28, 2005

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